NOV 1 5 2001

ATTACHMENT A

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K012544

APPLICANT INFORMATION

Date Prepared: August 6, 2001

Name: Vascular Architects, Inc.
Address: 1830 Bering Drive
San Jose, CA 95112

Contact Person: Jean Caillouette
Phone Number: (408) 392-7437
Fax Number: (408) 453-7970

DEVICE INFORMATION

Trade Name: VASCULAR ARCHITECTS **aSpire™ Covered Stent** and CONTROLLED EXPANSION™ Delivery System

Common Name: Tracheal Stent

Classification Name: Tracheal Prosthesis

Equivalent (Predicate) Devices:

K003173: Vascular Architects **aSpire™ Covered Stent** and Delivery Catheter

Intended Use:

The VASCULAR ARCHITECTS **aSpire Covered Stent** and CONTROLLED EXPANSION Delivery System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms and for the treatment of benign strictures after all alternative therapies have been exhausted.

Comparison To Predicate Device:

VASCULAR ARCHITECTS **aSpire Covered Stent** and CONTROLLED EXPANSION Delivery System has the same intended use and technological characteristics as the predicate device.

The materials used to manufacture the VASCULAR ARCHITECTS **aSpire Covered Stent** and CONTROLLED EXPANSION Delivery System are similar to the materials used to manufacture the predicate device.

The available lengths and diameters of the VASCULAR ARCHITECTS **aSpire Covered Stent** and CONTROLLED EXPANSION Delivery System are similar to the lengths and diameters available for the predicate device.

Non-clinical Test Results:

Bench testing was conducted comparing the VASCULAR ARCHITECTS **aSpire Covered Stent** and CONTROLLED EXPANSION Delivery System to the predicate device. Results of bench testing performed demonstrate that the mechanical integrity and device performance of the subject device is substantially equivalent to that of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2001

Ms. Jean M. Caillouette
Manager, Regulatory Affairs
Vascular Architects, Inc.
1830 Bering Drive
San Jose, California 95112

Re: K012544
Trade/Device Name: VASCULAR ARCHITECTS aSpire™ Covered Stent and CONTROLLED EXPANSION™ Delivery System
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: October 26, 2001
Received: October 31, 2001

Dear Ms. Caillouette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walky MS

for

Celia M. Witten, Ph.D., M.D.
Director
Divison of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND
D.O.
d/t:HFZ-410:SRArepalli:bxw:11/13/01

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Indications for Use

510(k) Number (if known): K012544

Device Name: VASCULAR ARCHITECTS **aSpire™ Covered Stent** and CONTROLLED EXPANSION™ Delivery System

Indications for Use: The VASCULAR ARCHITECTS **aSpire™ Covered Stent** and CONTROLLED EXPANSION™ Delivery System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms and for the treatment of benign strictures after all alternative therapies have been exhausted.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____

(Optimal Format 1-2-96)